



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/089,997

09/23/2002

Barrie Hayes-Gill

469.1094

5818

21171 7590 04/30/2008

STAAS & HALSEY LLP
SUITE 700
1201 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

BERTRAM, ERIC D

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/089,997	Applicant(s) HAYES-GILL ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-47 and 63-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-47 and 63-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 25-47 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25-47 and 63-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 25, 63 and 65 recite the limitations "the abdomen", "the mother", "the heart rate of the fetus", "the heart rate of the mother" and "the time interval" in each claim. There is insufficient antecedent basis for these limitations in the claims. Since claims 26-47, 64 and 66-69 depend from claims 25, 63 and 65 respectively, these claims are rendered indefinite by their association.

5. Furthermore, claim 26 is indefinite because it states that ECG signals from two detectors are utilized to determine the heart rate of the fetus. However, claim 25 requires that only a signal detector be utilized without utilizing any other detected signals. The signals detected from a second detector would constitute "other detected signals."

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Art Unit: 3766

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 25-47 and 63-69 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 25, 63 and 65 recite "electrodes placed on the abdomen of the mother." This constitutes an inferential resuscitation of the body as a structural limitation in the claim, which is not allowed under 35 USC 101. The examiner recommends changing it to read as --electrodes adapted to be placed on an abdomen of a mother--. Since claims 26-47, 64 and 66-69 depend from claims 25, 63 and 65 respectively, these claims are rendered non-statutory by their association.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 25-27 and 30-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (US 6,115,624, hereinafter Lewis) in view of Richter et al. ("Fetal ECG Extraction with Nonlinear State-Space Projections", hereinafter Richter).

12. Lewis discloses an apparatus for detecting fetal and/or maternal heart rate, wherein a plurality of ECG electrodes may be located on a lower surface of a pad which is secured to a pregnant women's abdomen (see col. 2, lines 33-65). Fetal and/or maternal ECG activity may be detected with the array of electrodes (see col. 2, lines 50-55), and processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60) by processing only ECG signals received from electrodes on the abdomen. Lewis does not specifically disclose that the processor utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate. However, detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and corresponding time intervals. In the alternative, it is well known in the art to detect heart beats of the mother by determining when the ECG

peaks reach a maximum (i.e., QRS peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between QRS peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. such that detection of the maternal heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate by well known and accepted medical methods.

13. Lewis does not disclose, however, only processing the ECG signals without using any other detected signals, but discloses determining the maternal ECG and fetal ECG by cancelling out the maternal ECG using acoustic signals. Attention is directed to the secondary reference of Richter, which discloses a method of processing ECG's recorded from the surface of a mother to determine the fetal ECG as well as the maternal ECG without utilizing any other detected signals (See Introduction and fig. 3). This method is preferred to cancellation techniques, such as Lewis, since Richter teaches that exogenous noise is not removed through cancellation (see introduction). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify Lewis by only using the ECG signals detected from the abdomen to determine fetal and maternal ECG's as taught by Richter, which can then be used to determine fetal and maternal heart rate as disclosed by Lewis.

14. With respect to claims 26 and 27, Lewis discloses that the array of electrodes includes at least two detectors to detect the heart beats of the fetus, each

detector including at least two electrodes (active electrodes 42 and common or reference electrode 41; see col. 4, line 55 - col. 5, line 6).

15. With respect to claim 31, Lewis discloses that the ECG signal may be utilized by the processor circuitry to derive the fetal and/or maternal heart rate, which may then be displayed on a video display or other monitoring device (see col. 2, lines 58-61). The processed data may be displayed in a useful manner, e.g., on digital display or a chart recorder (see col. 9, lines 1-10).

16. With respect to claims 30, 32, and 36-37, bandpass filters are well known to filter noise components from a detected ECG. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. such that bandpass filters are utilized in the signal processing of the ECG in order to reduce noise and obtain a more accurate ECG signal.

17. With respect to claims 33 and 35, Lewis teaches that the processor circuitry may compare the detected signals to a database stored in the memory circuitry to further facilitate the heart rate information in the signals. For example, the database may include information such as standard maternal and/or fetal heart signals which may be compared to the detected signals in order to more accurately derive the desired actual heart rate (see col. 10, lines 43-51).

18. With respect to claims 34 and a portion of claim 40, subtracting a maternal component from a composite ECG is well known in order to obtain the fetal ECG only (e.g., see U.S. Patent No. 4,781,200 to Baker at col. 8, lines 20-40 or col. 10, lines 55-65). It would have been obvious to one having ordinary skill in the art at the time of

Art Unit: 3766

applicant's invention to modify the monitoring device of Lewis to utilize the standard maternal heart signal stored in the above-described database in order to obtain the fetal ECG only and monitor the well-being of the fetus.

19. With respect to claims 38-39 and a portion of claim 40, Lewis discloses that the processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60). Lewis does not specifically disclose that the processor utilizes ECG peaks in order to determine the fetal heart rate. However, detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and corresponding time intervals. In the alternative, it is well known in the art to detect heart beats by determining when the ECG peaks reach a maximum (i.e., ECG peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between ECG peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis such that detection of the fetal heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the fetal heart rate by well known and accepted medical methods.

20. With respect to claim 41, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to aggregate the heart rate over a predetermined time period in order to detect sustained low or high fetal heart rates.

21. With respect to claim 42, Examiner considers the apparatus portable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Friday from 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766

/E. D. B./
Examiner, Art Unit 3766
April 28, 2008